

Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR)

Data Submission Request

Contents

FITBIR Informatics System Data Submission Request 2

 Steps to Request to Submit Data and/or Images to FITBIR 2

 Data Submission Agreement for the FITBIR Informatics System 2

FITBIR Information Security Best Practices 5

 Best Practices 5

 Security Standards 6

Submitter Information and Certifications 7

FITBIR Informatics System Data Submission Request

The FITBIR Data Access & Quality Committee (DAQ) approves submission of data and/or images to the FITBIR Informatics System. The DAQ will review the Informatics System Data Submission Request and will decide whether to permit the submission based on the expectations outlined in the FITBIR policy. In the event that submissions raise concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the DAQ will consult with other experts as appropriate. In unusual circumstances, when people are denied approval to submit data, appeals may be sent to the FITBIR Policy Committee.

Submitters may use this Informatics System Data Submission Request to 1) only submit data to FITBIR or 2) submit data to FITBIR and for subsequent analysis with FITBIR tools by the Submitter. Both types of requests are subject to approval by the DAQ. Completing this Informatics system Data Submission Request is a necessary step to submit data to FITBIR. Access to other data within FITBIR for analysis purposes may be subject to the FITBIR Informatics System Data Access Request and procedures.

Steps to Request to Submit Data and/or Images to FITBIR

1. Contact NIH through FITBIR-help@mail.nih.gov to set up an introductory phone call to begin planning for data submission. The FITBIR staff will discuss with investigators a) data submission expectations; b) supporting materials submission expectations; c) data access preferences; d) technical specifications; and e) data accuracy as it relates to FITBIR. Contacting NIH two months before the desired date of submission is recommended to provide ample time to resolve technical and other issues.
2. Review the capabilities of FITBIR at <http://fitbir.nih.gov>.
3. If FITBIR can accommodate the data per discussions with the FITBIR staff, read the FITBIR Informatics System Data Submission Agreement (SA) and complete and sign the SA on the Submitter Information and Certifications form (below).
4. Request a FITBIR portal account under the "Request an Account" tab. When creating an account, request access to submit data to FITBIR (Study Privilege). Requests for access to the Global Unique Identifier (GUID) client software may be submitted at this time.
5. When requesting to create a Study in FITBIR, submit the Data Submission Agreement (SA).
6. Data submission review: The DAQ will review requests to submit data to the FITBIR Informatics System. Such reviews are generally completed within 10 business days.
7. The DAQ will notify FITBIR staff if the submission request has been approved and an account will then be provided.

Once a Submitter has permissions to submit data to FITBIR, he or she should follow the steps for data submission as defined at <https://fitbir.nih.gov/content/contribute-data>.

Data Submission Agreement for the Federal Interagency Traumatic Brain Injury Research Informatics System

I request approval to submit data and/or images to the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics system for the purpose of sharing data for research purposes. I agree to the following terms:

1. Research Project. These data will be submitted solely in connection with the "Research Project", specifically indicated and described in the Submitter Information and Certifications section.

Data submitted to FITBIR may be made available by NIH and DOD for either collaborative research (i.e., to accelerate research on ongoing studies) or general research purposes (i.e., meta-analyses and other secondary uses of the data).

This Submission Agreement (SA) covers only the Research Project as contemplated in the Submitter Information and Certifications section. Submitter will submit a completed SA (this document) for each research project for which submission is requested.

2. Non-transferability of Agreement. This SA is not transferable. Submitter agrees that substantive changes Submitter makes to the Research Project requires execution of a new SA, in which the new Research Project is designated. If the Submitter changes institutions and wishes to retain submission privileges to FITBIR, a new SA in which the new institution acknowledges and agrees to the provisions of the SA is necessary.

3. Use of NIH Global Unique Identifier Client and Common Data Elements. Submitter has used the software program provided free-of-charge by NIH to assign GUIDs to each participant as described in the Policy for the FITBIR Informatics System ([FITBIR Policy](#)) and has re-sorted the data according to the GUID. Submitter also agrees to use the Interagency [TBI Common Data Elements](#) as appropriate for their research. FITBIR staff will work with researchers to map their study variables to specific CDEs.

4. Non-Identification of Subjects. Submitter agrees the data and/or images have been 'de-identified' according to the following criterion: the identities of subjects cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data users (Submitter further agrees not to disclose the identities of research participants to FITBIR in the future and to verify that data and/or images lack identifiers after submission. Submitter agrees to notify FITBIR as soon as possible if, upon review of FITBIR data, the Submitter discovers identifying information in that data.

5. Data Disclaimers. Submitter agrees that DOD and NIH do not and cannot warrant the results that may be obtained by using any data or data analysis tools included in FITBIR. DOD and NIH disclaim all warranties as to the accuracy of the data in FITBIR or the performance or fitness of the data or data analysis tools for any particular purpose.

6. Supporting Materials. Submitter agrees to provide FITBIR with supporting information and documentation ("Supporting Materials") to enable efficient use of the submitted data by investigators unfamiliar with the data. For example:

- Research protocol(s)
- Questionnaire(s)
- Study manuals
- Description of variables measures
- Other supporting documentation, as appropriate

7. Data Accuracy. Submitter certifies to the best of his/her knowledge and belief that the data submitted to FITBIR are accurate. Submitter also agrees to perform the specified quality control activities within a timeframe specified by the FITBIR Policy (see above). Submitter further agrees to notify FITBIR as soon as possible if, upon review of FITBIR data, the Submitter discovers data quality concerns.

8. Notification to DOD and NIH of Publication. Prompt publication or other public disclosure of the results of the Research Project is required. Submitter agrees to notify DOD and NIH as to when and where a publication (or other public disclosure) of a report from the Research Project will appear. Notification of such publications can occur by sending an email to FITBIR-help@mail.nih.gov with the title, authors, place of publication, and publication date. Notification of such publications can also occur by sending to FITBIR an updated biographical sketch or CV of the publishing author.

9. Data Access for Research. Submitter agrees that data and Supporting Materials submitted to FITBIR may be accessed and used broadly by qualified researchers for research and other activities as authorized by and consistent with law. This access may result in duplication of research data.

10. Non-Research Access. Submitter acknowledges that data and Supporting Materials submitted to FITBIR become U.S. Government records that are subject to the Freedom of Information Act (FOIA). DOD and NIH are required to release Government records in response to (FOIA) requests unless they are exempt from release under one of the FOIA exemptions. Submitter further acknowledges that data and Submitting Materials may be used or released consistent with law.

11. Acknowledgments. In any and all publications based upon dataset(s) submitted to FITBIR, Submitter agrees to cite FITBIR, the relevant FITBIR dataset identifier (a serial number), and the Submitters' federal research funding sources in each publication to which such datasets contribute (for abstracts, as space allows). The publication should include the following acknowledgement:

Data used in the preparation of this article reside in the Department of Defense (DOD) and National Institutes of Health (NIH)-supported Federal Interagency Traumatic Brain Injury Research Informatics Systems (FITBIR) in [dataset identifier]. This manuscript reflects the views of the authors and does not reflect the opinions or views of the DOD or the NIH.

Submitter agrees to acknowledge the contribution of the FITBIR bioinformatics platform in any and all oral and written presentations, disclosures, and publications resulting from substantive analyses of data using FITBIR tools. The manuscript should include the following acknowledgement:

Data and research tools used in the preparation of this article reside in and were analyzed using the Department of Defense (DOD) and National Institutes of Health (NIH)-supported Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR). FITBIR is a collaborative biomedical informatics system created by DOD and NIH to provide a national resource to support and accelerate research in traumatic brain injury. Dataset identifier: [provide]. This manuscript reflects the views of the authors and does not reflect the opinions or views of the DOD or NIH.

12. Non-Endorsement; Liability. Submitter agrees not to claim, infer, or imply endorsement by the United States Government, the Department of Defense, the Department of Health & Human Services, or the National Institutes of Health of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s). The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

13. Submitter's Compliance with Institutional Requirements. Submitter acknowledges that these data were collected in manner consistent with all applicable laws and regulations, as well as institutional policies. Submitter further acknowledges that the data were collected pursuant to an informed consent that is not inconsistent with the data submission, and that the data submitted were collected in accordance with NIH and DOD regulations, or applicable foreign law concerning the protection of human subjects, and other applicable U.S. federal and state laws, if any.

14. Submitter's Permission to Post Information Publicly. Submitter agrees to permit DOD and NIH to summarize and release for public use on the FITBIR Web site the Supporting Materials along with the Submitter's name and organizations/institutional affiliation.

15. Privacy Act Notification. The Submitter agrees that information collected from the Submitter, as part of the SA, may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below from the Submitter comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the [Privacy Act System of Record Notice 09-25-0200](#) covering "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD." The primary uses of this information are to document, track, and monitor

and evaluate the submission of data from clinical, basic, and population-based research activities and to notify Submitters in the event a potential error in the dataset is identified or in the event of updates or other changes to the database.

The Federal Privacy Act protects the confidentiality of the Submitter's NIH and DOD records. DOD and NIH will use the data collected for the purposes described above. In addition, the Act allows the release of some information in the Submitter's records without the Submitter's permission; for example, if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for submitting data to FITBIR.

16. Security. Submitter acknowledges the expectations set forth by the attached "FITBIR Information Security Best Practices" for the use and security of data.

17. Amendments. Amendments to this SA must be made in writing and signed by authorized representatives of both parties.

18. Termination. Either party may terminate this SA without cause provided 30 days written notice to the other party. FITBIR will retain a copy of all data already submitted to FITBIR for which data quality activities have been completed, except in the event that research participants withdraw consent for sharing of their data through the FITBIR repository and DOD and NIH are informed by the Submitter to withdraw the data. Submitters agree to immediately report violations of FITBIR Policy to the FITBIR DAQ. Additionally, DOD and NIH may terminate this agreement with 5 days written notice if the agencies determine, in their sole discretion, that the Submitter has committed a material breach of this SA. The agencies may, in their sole discretion, provide Submitter with 30 days' notice to remedy a breach before termination. Closed accounts may be reactivated upon submission of an updated Submission Request and SA.

19. One-Year Term and Access Period. Researchers who are granted permission to submit data to FITBIR receive an account that is valid for a period of one year. This SA will automatically terminate at the end of one year. An account may be renewed upon recertification of a new SA. Accounts that remain inactive for 12 consecutive months may be closed at the discretion of DOD and NIH.

FITBIR Information Security Best Practices

The purpose of these Security Best Practices, which are subject to applicable law, is to provide minimum security standards and best practices for individuals who use FITBIR to submit, access, and analyze data. Keeping FITBIR information secure through these best practices is important. Subject to applicable law, Submitters agree to immediately report breaches of data confidentiality to the FITBIR DAQ.

Best Practices

- Do not attempt to override technical or management controls to access data for which you have not been expressly authorized.
- Do not use your trusted position and access rights to exploit system controls or access data for any reason other than in the performance of the proposed research.
- Ensure that anyone directed to use the system has access to, and is aware of, FITBIR Information Security Best Practices and all existing policies and procedures relevant to the use of FITBIR, including but not limited to, the FITBIR policy at <https://fitbir.nih.gov/content/policies-and-procedures>.
- Follow the FITBIR password policy which includes:
 - Choose passwords of at least seven characters including at least three of the following types of characters: capital letters, lower case letters, numeric characters and other special characters.
 - Change your passwords every six months.

- Protect your FITBIR password from access by other individuals—for example, store it electronically in a secure location.
- Notify FITBIR staff at FITBIR-help@mail.nih.gov of security incidents, or any incidents of suspected fraud, waste or misuse of FITBIR or when access to FITBIR is no longer required.

Security Standards

- Protect the data, providing access solely to authorized researchers permitted access to such data by your institution.
- Neither store nor transmit links between personally identifiable information and GUIDs.
- When you download FITBIR data, download the data to a secured computer or server with strong password protection.
- For the computers hosting FITBIR data, ensure that they have the latest security patches and are running virus protection software.
- Make sure the data are not exposed to the Internet or posted to a website that may be discovered by Internet search engines, such as Google or MSN.
- If you leave your office, close out of data files or lock your computer. Consider the installation of a timed screen saver with password protection.
- Avoid storing data on a laptop or other portable medium. If storing data on such a device, encrypt the data. Most operating systems have the ability to natively run an encrypted file system or encrypt portions of the file system (Windows = EFS or Pointsec and Mac OSX = File Vault).
- When finished using the data, destroy the data or otherwise dispose of them properly.

Submitter Information and Certifications

1. Submitter Information:

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title): _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____

Zip/Postal Code: _____ Country: _____

Telephone: _____ E-mail Address: _____

Institution's FITBIR Point of Contact Name (if different from the Submitter): _____

Institution's FITBIR Point of Contact Phone: _____ E-mail: _____

Research Project (Grant #): _____ Funding Agency: _____

Research Project (title and brief description): _____

2. Certificate of Confidentiality: applied obtained does not have

3. Attachments:

Upload electronic copies of the study protocol, questionnaires, study manuals, variables measured, and other supporting documentation, as appropriate via the FITBIR Website.

4. Signatures:

By signing and dating this SA as part of submitting Data to FITBIR, I certify that I will abide by the SA and the DOD and NIH principles, policies and procedures for the use of the FITBIR Informatics System. I further acknowledge that I have shared this document and the DOD and NIH policies and procedures with any research staff who will participate in the use of FITBIR.

Research Project PI Name: _____

PI Signature: _____ Date: _____

Requester Signature: _____ Date: _____

IRB Approval #: _____ Expiration Date: _____

Signing Official Name: _____ Title: _____

Signing Official Signature: _____ Date: _____

The Signing Official (SO) has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The label "Signing Official" is used in conjunction with the [eRA Commons](#). For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

If you are unable to identify your SO, contact the NIH eRA Commons Service Desk.

Inquiries about requests to Submit Data to FITBIR should be sent to FITBIR-help@mail.nih.gov